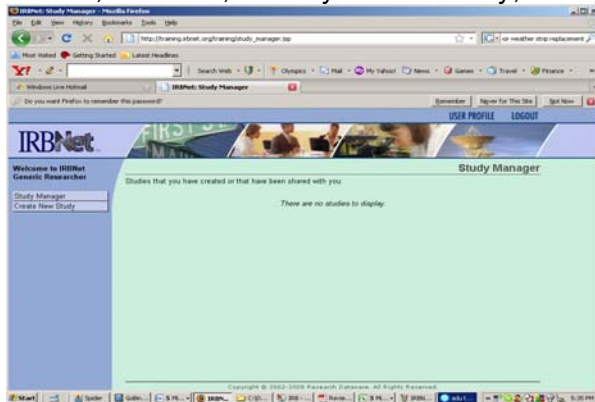


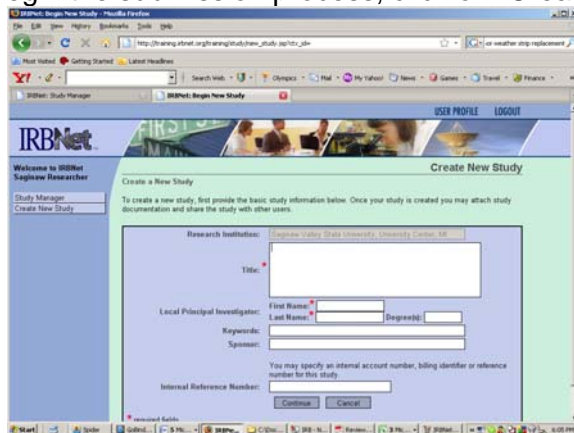
## SVSU IRB: Instructions for Submitting Project Materials via IRBNet

On September 6, 2008, the SVSU IRB will begin using IRBNet as the exclusive application process for all projects; we will no longer accept paper, email, or other application media. First-time users of IRBnet must register as a new user; if you have not done so, please peruse and follow the instructions titled “IRBNet new user registration.” These instructions assume you have already registered as an IRBNet user.

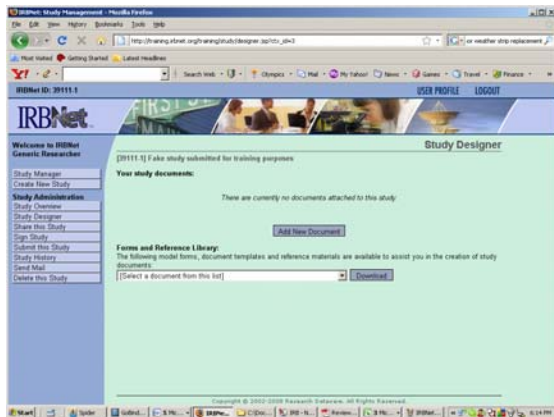
To begin or resume the submission process, go to [www.irbnet.org](http://www.irbnet.org) and enter the userid and password you obtained from the new-user-registration process. (Remember that the “Demo” icon is not for training; it will start a continuous video covering more about IRBNet than you want to know.) Once you log in, you will immediately be taken to the study manager, pictured below. If this is not your first study on IRBNet, then, unlike the picture below, you will see a list of study titles. If, however, this is your first study, then your screen will look just like this.



To begin the submission process, click on “Create New Study, after which you will see this

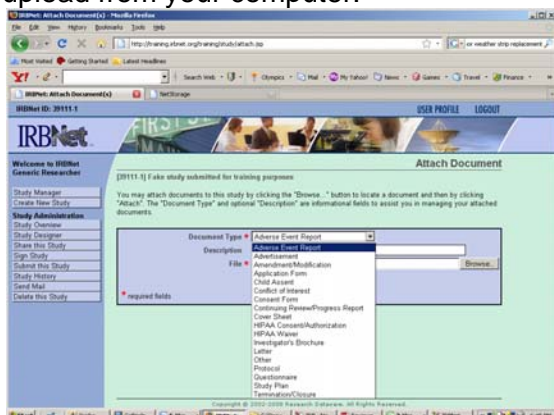


screen. The information required is, for the most part, obvious. The title and researcher’s names are required and will be used on all IRB records concerning this study. Optional information need not be entered and is solely for the researcher’s convenience. “Keywords” can be entered so that those who are involved in many studies can search through them on that basis. If the study has or will have a sponsor (e.g., NSF, Student Research and Creativity Institute, etc.), then you can enter that information, too. The “Internal Reference Number” is for the researcher’s use; you may, for example, enter a grant number or any other information that might be useful to you. After you enter the information, click on “Continue” and you will be taken to the “Study Designer” screen, pictured below.

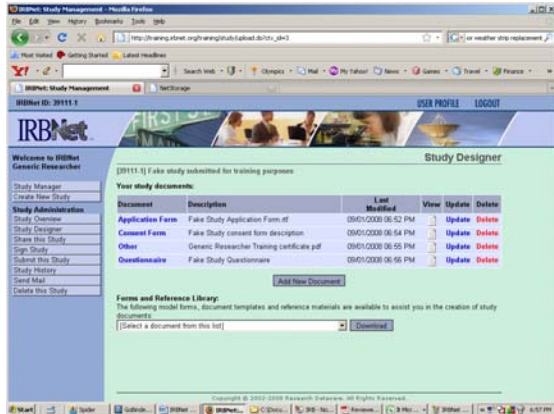


Through the Study-Designer screen you can upload a completed Request for Project Approval, a copy of your consent form, any questionnaires or other procedural materials, and your IRB training certificate. Just click on “Add New Document” and the upload process functions exactly like any other document-upload screen. You can upload any file formats; there are no restrictions. If you need a blank copy of the Request for Project Approval, you can download it by selecting it from the list of forms in the drop-down menu from the “Forms and Reference Library,” or you can download it from the SVSU IRB website. Note that “Study Designer” is for uploading completed documents and downloading blank documents only; all of the actual work on the documents, such as completing the items on the Request for Project Application, is done offline, using whatever word-processing or other software is appropriate.

Each time you click on “Add New Document,” you will see a screen like the one below, with a pull-down menu to make it easy to identify the type of document you are uploading to the study designer. Simply choose the type of document you are uploading, then add an expanded description if you want the document to be identified by anything other than its name, and then click on “Browse” to open a dialogue window through which you can choose which document to upload from your computer.

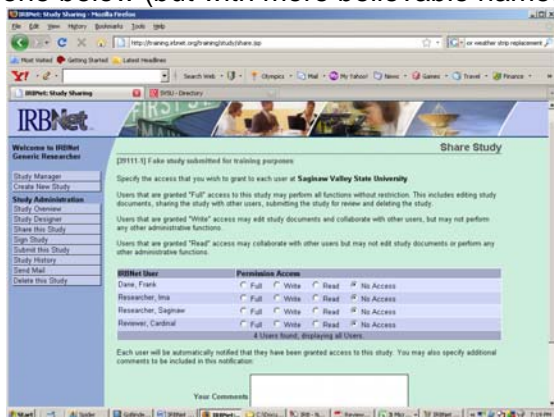


You do NOT have to upload all documents during the same session. You can come back to Study Designer as many times as is convenient. As you add documents, the screen changes to show you all of the documents that have been uploaded for this study; it will look something like the screen pictured below.



Notice that you can view each document in case you want to see what it looks like as stored on the IRBNet site, just in case you don't trust yourself to have uploaded the correct document or don't trust the IRBNet website to maintain a true copy. (Eventually, you'll come to trust IRBNet to maintain a true copy.) If you make changes to a document and want to upload the revision, click on "Update" and the document you upload will replace the one on IRBNet. If you change your mind and decide you don't want a particular document, click on "Delete" and it's gone. You can upload as many or as few documents as necessary for this particular study, but take note that these are the only documents that the IRB members will see; be sure to upload what is needed. All documents you upload belong to you; no one can alter them unless you give someone else write access to them. Indeed, no one can even read them until you give them read access or until you submit the study to the IRB. (Don't click on "submit" just yet; there are a few more things to be done.)

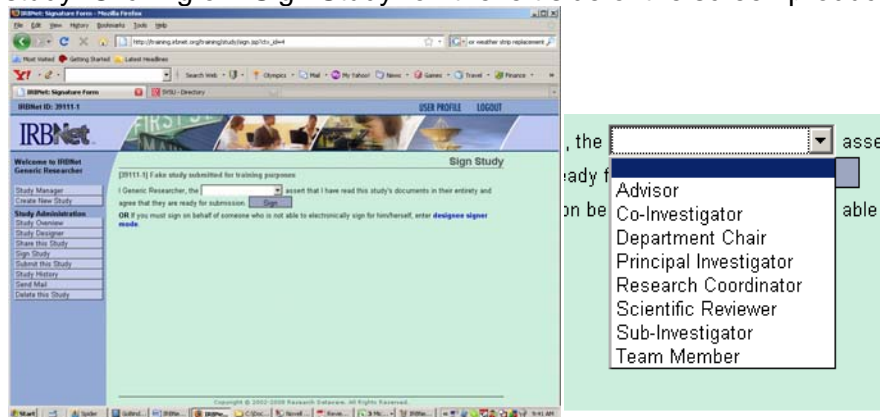
If you have co-investigators and/or a research supervisor, then you will need to share these materials with them so they can review them BEFORE you submit the study. When you click on "Share this Study" an informational screen will appear, on which the various ways to share a study are described. (If you think you need to use the "Multi-site" or "Transfer" options, call Ann Garcia, x-4484, or Frank Dane, x-2046, to make sure that is correct.) For the most part, you will want to "Share" the study, so click on the word "Share," after which you will see a screen through which you can search for Saginaw Valley State University (enter "Saginaw" in the search box); do not choose the Institutional Review Board as that will generate only names of IRB members. Once you choose SVSU as the organization, you will see a list of names or be invited to search for a name if the list is too long to display. You will see a screen similar to the one below (but with more believable names).



Note that the default value for all users is "No Access" (you will not appear in the list because IRBNet already knows you have full access to the study). You can grant each person a different kind of access, depending upon what IRBNet functions that person is required to do. All

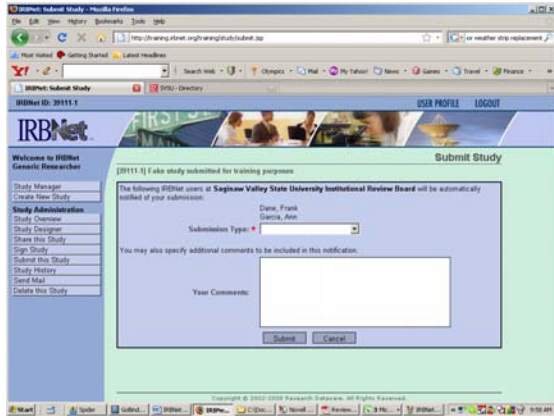
co-investigators and research supervisors should be granted at least Read access because they will have to examine the documents before signing off on the study. Any comments you place in the “Your Comments” box will be added to the email each person receives. Note that only registered IRBNet users will appear on the list; if you need to give access to others and they are not registered, then you will need to call, email, or otherwise communicate to them that they need to register with IRBNet. Once you click on “Save” the changes in access are immediate and you will see a list of all those with whom you shared the study and the access you granted them. You can make changes in access as often as is necessary. After you grant access, of any type, to others, you can communicate with them through the “Send Mail” icon on the left side of the screen. You can, for example, send an email to all of your co-investigators stating that you changed the consent form and they need to look at it to make sure they agree with the changes.

Once you have completed all uploads and granted necessary access, it is time to sign the study. Clicking on “Sign Study” on the left side of the screen produces the following screen.



Clicking on the down arrow to the right of the white box (just above the icon for sign) produces a pull-down menu from which you can select your status with respect to the study. Research supervisors should choose “Advisor” as their role. Note that according to SVSU Policy, all co-investigators and the research supervisor (if applicable) must sign each study before the IRB will review the project. This electronic signature is equivalent to an individual’s having signed a paper copy of an application; no signed paper copies of anything need to be submitted to the IRB.

When all documents have been uploaded and all signatures obtained, you are ready to submit the study to the IRB. This is done by clicking on “Submit this Study” on the left side of the screen. You will see a window through which you must choose the organization to which the study is submitted; use the search window (inputting “Sag” is probably sufficient for the search) and choose Saginaw Valley State University Institutional Review Board. Please be sure to submit your study to the correct IRB! After you choose the correct IRB, you will see a screen on which you can indicate the type of materials you are submitting.



Submission Type: \*

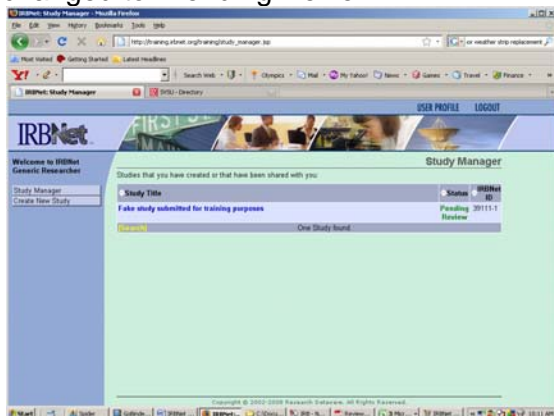
additional comments to

Your Comments:

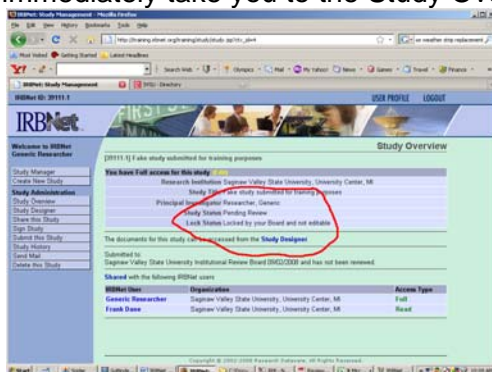
- Adverse Event
- Close/Final Report
- Continuing Review/Renewal
- Modification/Amendment
- New Study
- Other
- Reportable Event (Non-AE)
- Response/Follow-Up
- Revision

The pull-down menu enables you to declare the type of submission; please choose carefully as this declaration will have some impact on the manner in which the submission is handled. The review of your project could be delayed if the submission type is incorrect. The comments window enables you to provide any remarks you think might be helpful to the IRB's Administrative Assistant and/or members to the IRB Chair. After you click on the "Submit" icon at the bottom of the screen, you will see a confirmation screen. The Administrative Assistant and the Chair will automatically receive emails alerting them to the new submission, at which point processing and reviewing the study will commence.

If you return to the Study Manager screen, you will see that the status of the study has changed to "Pending Review."

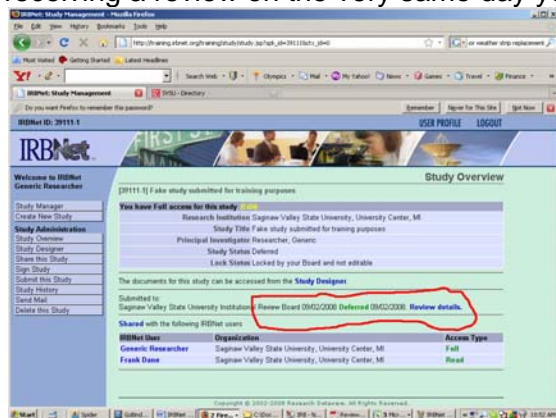


The study manager screen will display all studies with which you are associated, so you can easily keep track of all of the IRB-related research. Clicking on the name of any study will immediately take you to the Study Overview screen, which appears below.

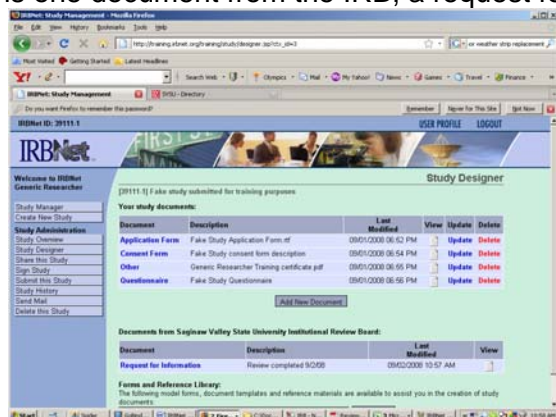


Notice that the study is locked while the review is pending. To enable an efficient review process, you are not allowed to change any of the study documents; you cannot, for example, submit a revision while the IRB reviewer is in the process of reviewing your study documents. Never fear, however, there is a mechanism for submitting revisions, which will be described after you learn how to examine the review that is provided.

You can check back with IRBNet as often as you wish, but you will receive an email when the IRB takes some action, any action, on your study. In the screen below, for example, you can see that the IRB deferred a decision on the project. The blue “Review details” indicator means that some documents from the IRB have been posted for your inspection. (Please note that receiving a review on the very same day you submitted a new study is not likely to happen.)

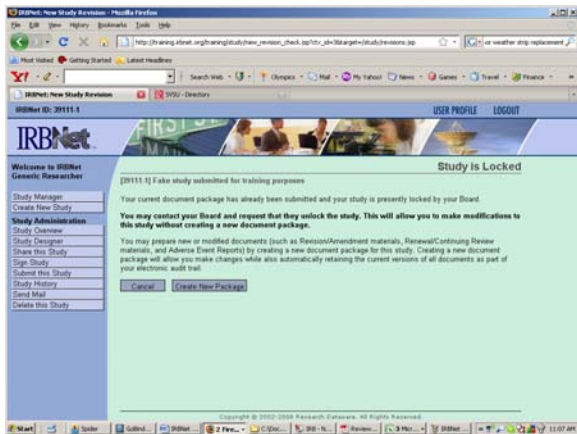


To see the reviewer’s comments, you only need to click on the “Study Designer” icon on the left side of the screen. In the study-designer screen below, for example, you can see that there is one document from the IRB, a request for information. Clicking on

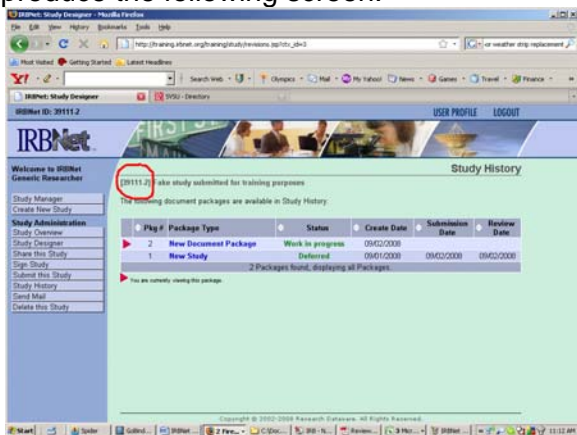


the paper icon under the word “view” to the right side of the screen will open the document. In this case our Generic Researcher would need to provide whatever information is requested by the reviewer before further action would be taken. If you have been paying attention, however, you will remember that the study is “locked” and Generic Researcher can’t change any documents or add new ones.

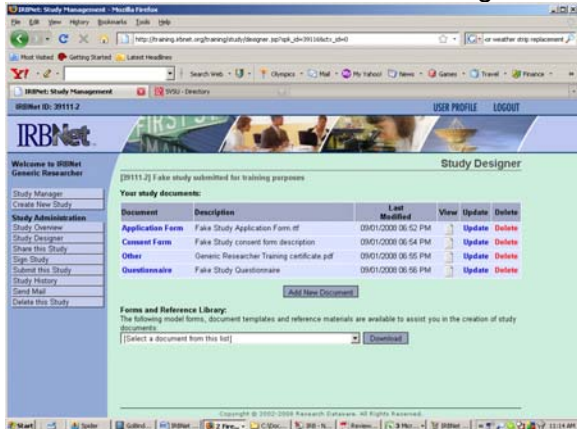
IRBNet handles the process of amending or adding new documents through the creation of a new “package” within the study. Clicking on the “Add New Document” icon produces the following screen. From this screen, one can create a new package that



contains the information requested by the IRB Reviewer. (One can also create a new package by going to the “Study History” screen.) Suppose, for example, that the IRB Reviewer requested a revision of the consent form; Generic Researcher would make the requested revisions to the document stored on his or her computer and then click on “Create New Package,” which would produce the following screen.

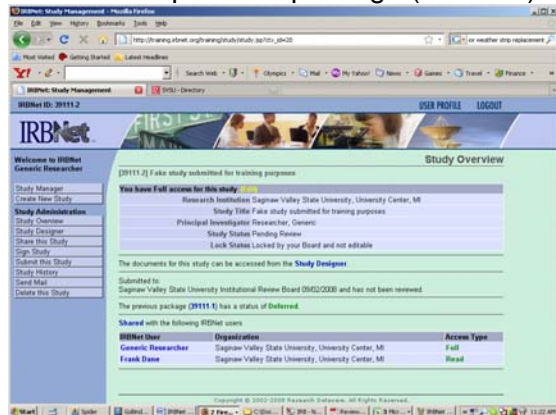


Notice that the study number has changed to “-2”; this indicates that one is now working on the second package for the study. Clicking on “New Document Package” in the blue font will bring the researcher back to the Stud Designer Page, which will look like this.

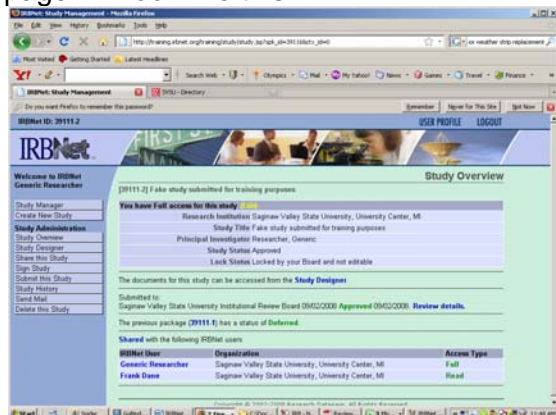


Everyone who had access to the first package has exactly the same access to the second package; access applies to the entire study. All of the original documents are there, and new documents, such as the revised Consent Form, can be added in exactly the same way the

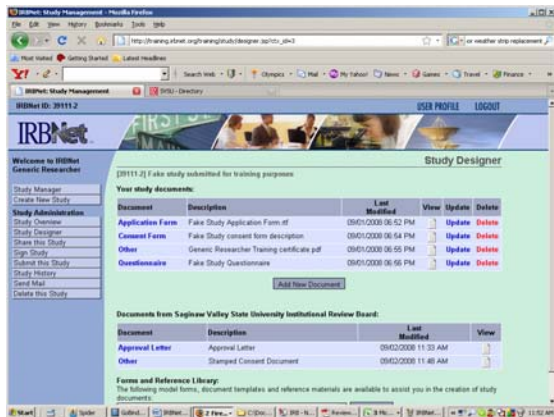
original documents were added. You can keep all of the original documents or you can delete some of them, say the consent form, and upload the revised consent form. Or, you can choose to “Update” the original consent form, which will replace the original document with the revision you upload. Because this is the second package, all of the original documents will still be retained for audit purposes in the first package. Once the proper documents are uploaded to this package, it still needs to be signed and submitted, after which the IRB Reviewer will be able to examine the new documents. This process of review and package creation can occur as many times as necessary in order to produce a study that can be approved by the IRB. Once the new package is submitted, the Study Overview page will look like the screen illustrated below. Notice that the new package has yet to be reviewed, but there is an indication of the status of the previous package (39111-1).



After the review process is completed and the study has been approved, the study overview page will look like this.



There is an indication that the study has been approved, but notice that you have to go to the Study Designer page in order to see the documents from the IRB, the Approval Letter and the Stamped Consent Form. The Study Designer page now looks like this.



The Approval Letter and the Stamped Consent Form can be viewed by clicking on the paper icon under the word "View" on the right side of the screen. These can be downloaded and printed for use later and will remain associated with this study forever.

If the study lasts longer than one year, you will need to renew the project, in which case you would create yet another package and the process would continue just as before.

If you have any questions about this process, or need an individual training session, please contact either the IRB Administrative Assistant, Ann Garcia (x-4474), or the IRB Chair, Frank Dane (x-2046).